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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,561

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James F. Zucherman

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COATS & BENNETT/MEDTRONIC

1400 CRESCENT GREEN

SUITE 300

CARY, NC 27518

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,561

Applicant(s)

ZUCHERMAN ET AL.

Examiner

JERRY CUMBERLEDGE

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 50 and 52-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Varlet (US Pat. 4,779,816).

Varlet discloses an implant to be implanted between adjacent first and second spinous processes, the implant comprising: a planar unitary body (Fig. 1, ref. 1) having a first end (Fig. 1, ref. 3), a second end (Fig. 1, ref. 2), and opposed sides extending therebetween (Fig. 1, ref. 15 and 16); a first leg (Fig. 1, ref. 12) extending from the first end along the second side (Fig. 1, ref. 16); a second leg (Fig. 1, ref. 11) extending from the second end along the first side (Fig. 1, ref. 15); a first saddle (Fig. 1, ref. 5) disposed at the first end between the first leg and the first side so as to receive the first spinous process when the implant is implanted; a second saddle (Fig. 1, ref. 4) disposed at the second end between the second leg and the second side so as to receive the second spinous process when implanted; a first fastener (Fig. 3, near ref. 5) coupled with the first saddle so as to secure the first spinous process to the first saddle; a second fastener (Fig. 3, near ref. 4) coupled with the second saddle so as to secure the second spinous process to the second saddle. At least one of the first or second fasteners comprises a tether (Fig. 3).

Varlet discloses an implant for use as an interspinous process implant between a first spinous process and a second spinous process, the implant comprising: planar unitary body (Fig. 1, ref. 1) having a first end (Fig. 1, ref. 3) that defines a first saddle (Fig. 1, ref. 5) and a second end (Fig. 3, ref. 2) that defines a second saddle (Fig. 1, ref. 4); a first tether (Fig. 3, near ref. 5) coupleable with the first saddle so as to surround the first spinous process when the first saddle receives the first spinous process; a second tether (Fig. 3, near ref. 4) coupled with the second saddle so as to surround the second spinous process when the second saddle receives the second spinous process and the planar body extends between and separates the spinous processes. The first tether is configured to retain the first spinous process relative to the first saddle and the second tether is configured to retain the second spinous process relative to the second saddle. The first saddle further defined between a first leg (Fig. 1, ref. 12) and a first side (Fig. 1, ref. 15) of the planar body and said second saddle further defined between a second leg (Fig. 1, ref. 11) and a second side of the planar body (Fig. 1, ref. 16) wherein the first tether is associated with the first leg (Fig. 3) and the first side of the planar body and the second tether is associated with the second leg and the second side of the planar body (Fig. 3).

Varlet discloses an interspinous process implant comprising: a unitary central planar body (Fig. 1, ref. 1) with first (Fig. 1, ref. 5) and second saddles (Fig. 1, ref. 4) located on opposite sides of the planar body and configured to receive adjacent spinous processes (Fig. 1), the interspinous process implant having at least one tether (Fig. 3, near ref. 4) secured to at least one saddle so as to retain the interspinous process

implant between the interspinous processes and maintain separation between the interspinous processes (Fig. 3). The planar body is configured to distract the adjacent spinous processes (Fig. 3).

Varlet discloses an implant for relieving pain associated with a spine, comprising: a unitary planar body (Fig. 1, ref. 15) having a continuous surface positionable between two adjacent spinous processes (Fig. 1), the planar body having a first end (Fig. 1, ref. 3) and a second end (Fig. 1, ref. 2); the first end of the planar body defining a first saddle (Fig. 1, ref. 3) configured to receive the first spinous process (Fig. 1); the second end of the planar body defining a second saddle (Fig. 1, ref. 2) configured to receive the second spinous process (Fig. 1); a first fastener (Fig. 3, near ref. 5) associated with the first saddle so as to retain the first spinous process in the first saddle; a second fastener (Fig. 3, near ref. 4) associated with the second saddle so as to retain the second spinous process in the second saddle (Fig. 1). The first saddle is associated with a first leg (Fig. 1, ref. 18) and first side of the planar body (Fig. 1, ref. 15) and the second saddle is associated with a second leg (Fig. 1, ref. 13) and a second side of the planar body (Fig. 1, ref. 1). The first fastener is secured through a first bore (Fig. 1, ref. 5) in the first leg and is securable to the first side of the planar body (Fig. 1) and said second fastener is secured through a second bore (Fig. 1, ref. 4) in the second leg and is securable to the second side of the planar body (Fig. 1).

With regard the statement of intended use and other functional statements (e.g. ...an implant to be implanted between first and second spinous processes...), they do not impose any structural limitations on the claims distinguishable over the device of

Varlet, which is capable of being used as claimed if one so desires to do so. In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varlet (US Pat. 4,779,816) in view of Collins (US Pat. 276,097).

Varlet discloses the claimed invention except for the first fastener is separate from said second fastener; the planar body, when implanted, extends in compression between the first spinous process at the first end and the second spinous process at the second end so as to distract the adjacent spinous processes.

Collins discloses a device that comprises a unitary body (Fig. 1) that comprises multiple fasteners (Fig. 3) associated with different ends of the device (Fig. 3, refs. a

and b). The device allows for the coupling of multiple fasteners (column 1, lines 7-10), which would give greater adjustability to the device (*i.e.* one can change the length of the fasteners) and would give the user the ability to couple smaller fasteners together to create a longer overall reach of the device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Varlet with the ability to couple and contain multiple fasteners of Collins, in order to allow for greater adjustability of the device and to allow a user to couple smaller portions of fasteners together to create a longer overall reach of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733